

performed as described for the standard protocol. Each symbol is a plate with a different lot number. Values are the mean of triplicate determination  $\pm$  standard deviation.

Figure 17 shows the day to day reproducibility of the ELISA assay for antibodies to SQE. Plates were coated with 10 nmol of SQE. PBS-2% BSA was used as a blocker /diluent. Experiments 1 and 2 were done on separate days using the standard protocol. Values are the mean of triplicate determination  $\pm$  standard deviation.

Figures 18-22 shows the results of the experiments described in Example 19, illustrating the applicability of the method of the present invention to detecting anti-squalene antibodies in human sera.

#### (G) DETAILED DESCRIPTION OF THE INVENTION

The present invention is monoclonal antibody that specifically binds to squalene, and methods for producing the monoclonal antibody. A monoclonal antibody that specifically binds to squalene has been deposited in the American Type Culture Collection, and has received Accession No. \_\_\_\_\_. "Squalene" refers to a hydrocarbon of the chemical formula  $C_{30}H_{50}$  [2, 6, 10, 15, 19, 23-hexamethyl-2, 6, 10, 14, 18, 22-tetracosahexaene], CAS Number [111-02-4].

The present invention is also the use of that monoclonal antibody, or a segment or portion thereof, in an immunoassay for the detection of anti-squalene antibodies. "Anti-squalene antibody" refers to an antibody capable of complexing with squalene. Such an antibody may complex with squalene, or with any antigenic epitope presented by squalene.

The present invention is also directed to an immunoassay for detecting anti-squalene antibodies. In preferred embodiments of the invention, the immunoassay is specific for anti-squalene antibodies. In most preferred embodiments of the invention, the immunoassay is capable of differentiating between anti-squalene antibodies and anti-squalane antibodies.

The test sample may generally be any type of biological material containing antibodies. Such materials may be processed so that they are provided in a suitable form. The test sample is preferably provided from a bodily fluid, more preferably is provided